Remarks/Arguments

Claims 17-22 were rejected as failing to comply with the enablement requirement of 35 USC 112, first paragraph. Applicants request reconsideration and withdrawal of this rejection for the reasons that follow.

The present claims relate to treating bcr-abl positive leukemia that is resistant to imatinib (the compound of formula I) with a combination of imatinib and a CDK inhibitor. Applicants assert in the specification that the combination of the two agents is useful treatment for the condition. A synergistic effect is demonstrated for the combination of imatinib and the CDK inhibitor, flavopiridol. The specification teaches that other CDK inhibitors can be used in place of flavopiridol because the benefit is obtained by combining imatinib with an agent that provides the biological effect of CDK inhibition.

The stated bases for maintaining the rejection all relate to the ability of the CDK inhibitor to bind bcr-abl. However, the present specification and claims describe no such requirement. It is the CDK inhibitor's biological activity inhibiting CDK that makes it useful in the present method, and it is reasonable to expect that all agents having that effect will be useful in the present method.

In maintaining the rejection, the Examiner points out that CDK inhibitors are structurally diverse and hypothesizes that these structural differences may cause the different CDK inhibitors to bind bcr-abl differently. However, the present specification does not mention that the CDK inhibitor should bind to bcr-abl to have utility in the present method. The only requirement is for it to inhibit CDK. Thus, the example with the CDK inhibitor, flavopiridol, is sufficient to enable the skilled artisan to make and use the presently claimed invention.

Although it is reasonable to expect that some ratios of imatinib to CDK inhibitor could have more efficacy than others, the Examiner has not provided any information which would lead the skilled artisan not to expect some benefit from all of the combinations within the scope of the present claims. Therefore, the present claims are enabled over their entire scope.

The Examiner also points out that there are numerous known bcr-abl mutants, some of which are inhibited by imatinib and some of which are not. Since the present claims specify that the bcr-abl leukemia is resistant to imatinib, the present claims only embrace those bcr-abl positive leukemias wherein the bcr-abl is not sufficiently inhibited by imatinib. The present specification teaches that imatinib resistance can be overcome by a treatment which combines imatinib with an agent that provides for CDK inhibition. Since the CDK inhibitor used in the

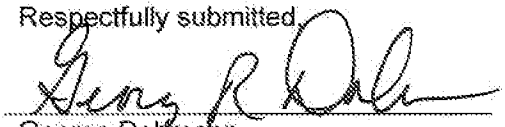
present method is only required to inhibit CDK, and the there is no teaching that the CDK inhibitor should also inhibit bcr-abl, it is reasonable to expect for all compounds that inhibit CDK to be useful in the presently claimed method. Therefore, the claims are fully enabled.

Applicants further note that claims 20 and 21 are limited to the use of the combination of imatinib and flavopiridol and that claim 21 specifies the ratio of flavopiridol to imatinib. Applicants assert that no basis has been provided for including these claims in the rejection.

Applicants request reconsideration and withdrawal of the enablement rejection for the reasons discussed above.

Entry of this amendment and reconsideration and allowance of the claims are respectfully requested.

Respectfully submitted,



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